IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,	)	
Plaintiffs,	)	C.A. No. 07-809-JJF
v.	)	**PUBLIC VERSION**
APOTEX INC., and APOTEX CORP.,	)	
Defendants.	)	

APOTEX CORP.'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS

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I. NATURE AND STAGE OF PROCEEDINGS

This is an action for patent infringement brought pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j). Plaintiffs AstraZeneca Pharmaceuticals, LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc. and Shionogi Seiyaku Kabushiki Kaisha ("Plaintiffs") claim that they own all substantial rights in U.S. patent no. RE37,314 ("'314 patent) covering the drug rosuvastatin calcium, which is used to treat high cholesterol, and is sold under the brand name CRESTOR®. Defendant Apotex Inc. is a Canadian Corporation that filed an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j)(2)(A), claiming that the '314 patent is invalid. Defendant Apotex Corp., located in Florida, was Apotex Inc.'s designated agent for purposes of accepting service of process for Apotex Inc. in the United States in connection with the ANDA filed by Apotex Inc.

Plaintiffs' Complaint alleges, pursuant to 35 U.S.C. § 271(e)(2)(A), that Apotex Inc. and Apotex Corp. have infringed the '314 patent by, among other things, submitting the ANDA for rosuvastatin calcium tablets. The Complaint was filed on December 11, 2007. (D.I. 1.) The Defendants were given until January 31, 2008 to answer or otherwise plead. (D.I. 8.)

II. SUMMARY OF ARGUMENT

Count I of the Complaint should be dismissed as to Apotex Corp. under Rule 12(b)(6) because the ANDA statute clearly states that any claim for patent infringement based on the filing of an ANDA may only be brought against the party that submits the application. In this case, it was Apotex Inc. that filed the application—not Apotex Corp. Apotex Corp. is merely the designated U.S. agent for purposes of accepting service of process for Apotex Inc. in the United States. Accordingly, Apotex Corp. is not a party subject to suit under the Hatch-Waxman Act.

Count II of the Complaint should be dismissed as to both Defendants under Rule 12(b)(1) because there is no case or controversy between Plaintiffs and Defendants under 35 U.S.C. § 271(a). Specifically, §271(a) requires an accused to make, use, offer to sell, sell, or import infringing inventions. However, Plaintiffs' only potential cause of action under the facts presented is limited to a claim under 35 U.S.C. § 271(e) based on the filing of the ANDA in suit, since there is no allegation that Defendants have actually made, used, sold, or imported any generic Crestor tablets. In addition, the allegations that form the basis for Count II (Defendants' alleged intent to sell rosuvastatin calcium tablets once the ANDA is approved) lack sufficient immediacy to give rise to an actual controversy.

The Complaint should also be dismissed as to Apotex Corp. under Rule 12(b)(7) in the event Apotex Inc.'s concurrently-filed Motion to Dismiss is granted. Apotex Inc. has filed a Rule 12(b)(2) motion to dismiss for lack of personal jurisdiction. In the event that motion is granted and Apotex Inc. is dismissed from the case, the remaining case against Apotex Corp. should be dismissed because the suit will be lacking an indispensable party—the actual party that submitted the ANDA that triggered this lawsuit in the first place.

III. STATEMENT OF FACTS

Apotex Inc. is a Canadian Corporation that manufactures and sells generic drugs, and has its headquarters in Toronto, Ontario, Canada. (*See* Complaint pars. 6, 13, D.I. 1.) Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") No. 79-145 to the FDA for a proposed drug product consisting of rosuvastatin calcium tablets. (Complaint par. 11.) A copy of the original ANDA submitted by Apotex Inc. is attached under seal as Exhibit A.

Apotex Corp. is a Delaware corporation with its headquarters in Florida. (Complaint par. 7.) Apotex Corp. was designated by Apotex Inc. under 21 C.F.R. § 271(e)(2)(A) as Apotex

Inc.'s agent in the United States authorized to accept service of process for Apotex Inc. in connection with ANDA No. 79-145.[1] (Complaint pars. 7, 14; Ex. A.) Apotex Corp. also countersigned ANDA No. 79-145 as required by the regulations.[2] (Ex. A.)

IV. ARGUMENT

A. Plaintiffs Cannot State A Claim Against Apotex Corp. For Direct Infringement Under 35 U.S.C. § 271(e)(2)(A) Because Apotex Corp. Is Not The ANDA Applicant

On a motion to dismiss for failure to state a claim under Rule 12(b)(6), a Complaint should be dismissed if the alleged facts, taken as true, fail to state a claim, or rather, the claimant cannot prove any set of facts consistent with his or her allegations that will entitle him or her to relief. *In re Warfarin Sodium Antitrust Litigation*, 214 F.3d 395, 397-98 (3d Cir. 2000). The Court must accept as true all well-pleaded allegations. However, "a court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." *Morse v. Lower Merion School Dist.*, 132 F.3d 902, 906 (3d Cir. 1997). Plaintiffs have failed to state a claim against Apotex Corp. under these standards.

In particular, Count I of the Complaint (seeking declaratory judgment of infringement under 35 U.S.C. § 271(e)(2)) fails to state a claim against Apotex Corp. upon which relief can be granted because Apotex Corp.'s only role with respect to the subject matter of this action is the fact that it is the designated agent of Apotex Inc. for purposes of accepting service of process for Apotex Inc. in connection with Apotex Inc.'s ANDA, and it countersigned the application.

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[1] 21 C.F.R. § 314.52(c)(7)(c) states that if the ANDA applicant does not reside or have a place of business in the United States, the applicant must provide "the name and address of an agent in the United States authorized to accept service of process for the applicant."

[2] 21 C.F.R. § 314.50(a)(5) states, "The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. If the person signing the application does not reside or have a place of business within the United States, the application is required to contain the name and address of, and be countersigned by, an attorney, agent or other authorized official who resides or maintains a place of business within the United States."

Under 35 U.S.C. § 271(e)(2)(A), only the entity that submits an ANDA to the FDA for approval as an applicant is subject to liability for infringement. Specifically, the statute provides that it "shall be an act of infringement to **submit** an [ANDA] application under section 505(j) of the Federal Food, Drug and Cosmetic Act ... if the purpose of such **submission** is to obtain approval ... to engage in the commercial manufacture, use, or sale of a drug ..." *Id.* (emphasis added). By its plain terms, only the party that **submits** the ANDA and applies for approval commits an act of infringement under § 271(e)(2)(A).

Apotex Corp., however, did not submit the ANDA in suit as an applicant. Apotex Corp. is only Apotex Inc.'s designated agent in accordance with the Federal Regulations. Therefore, Apotex Corp. is not considered an infringing party under the statute and the claims against it should be dismissed as a matter of law. Indeed, Courts have refused to permit claims against a party other than the ANDA applicant itself in analogous settings. In *Smithkline Beecham Corp. v. Geneva Pharms., Inc.,* 287 F. Supp. 2d 576 (E.D. Pa. 2002) and *Smithkline Beecham Corp. v. Pentech Pharms.,* Inc., No. 00 C 2855, 2001 WL 184804 (N.D. Ill. Feb. 20, 2001), each court refused to allow the patentee to assert a claim for direct infringement under 35 U.S.C. § 271(e)(2)(A) against the manufacturer of the active ingredient for the drug, holding that any such claim would be futile because that party was not the actual ANDA applicant and did not file the ANDA. *See Geneva,* 287 F. Supp. 2d at 584 ("By its terms, the Act limits liability for direct infringement to the party submitting the ANDA"); and *Pentech,* 2001 WL 184804, at *3 ("[T]he Court has been unable to locate, any authority supporting the proposition that a person other than an ANDA filer can be held liable for direct infringement under section 271(e)(2)(A)"). In fact, the *Geneva* court expressly rejected the notion that "a third party can be liable as a direct

infringer under Section 271(e)(2) based on its 'participation' in another party's filing of an ANDA." *Geneva,* 287 F. Supp.2d at 585.

In both *Geneva* and *Pentech,* the third-party manufacturers of active pharmaceutical ingredients used in the actual formulations for which the ANDAs in those cases were submitted to the FDA contributed more to the preparation and submission of their respective ANDAs than Apotex Corp. did here. With respect to ANDA No. 79-145, Apotex Corp. has effectively done nothing more than act as Apotex Inc.'s designated U.S. agent for transmitting the ANDA to the FDA and for accepting service of process. Applying the principles in *Geneva* and *Pentech*, this Court should dismiss Count I against Apotex Corp. because it is not the party that submitted the ANDA and it had, at best, only tertiary participation in an activity that constitutes a "highly artificial" act of infringement in the first place. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

B. COUNT II SHOULD BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION

This Court should also dismiss Count II pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, because there is no case or controversy between Defendants and Plaintiffs under 35 U.S.C. Section 271(a).[3] The Declaratory Judgment Act ("DJA") provides that, "in a case of *actual controversy* within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a) (emphasis added). "A party seeking to base jurisdiction on the Declaratory Judgment Act bears the burden of proving that the facts alleged, 'under all the circumstances, show that there is a substantial controversy,

[3] §271(a) requires an accused to make, use, offer to sell, sell, or import infringing inventions, acts not alleged here.

between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343 (Fed. Cir. 2007) (quoting *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007)).

> Plaintiffs claim infringement under Section 271(a) based on the following allegations:
>
> 27. Upon information and belief, Apotex Inc. and Apotex USA have made substantial preparations to sell Apotex Rosuvastatin Calcium Tablets labeled for the same dosages as the Crestor(r) products.
>
> 28. Upon information and belief, Apotex Inc. and Apotex USA intend to commence sales of Apotex Rosuvastatin Calcium Tablets immediately upon receiving approval from the FDA.
>
> 29. The manufacture, importation, sale and offer for sale of Apotex Rosuvastatin Calcium Tablets, once approved by the FDA, will directly infringe, induce, and/or contribute to the infringement of one or more claims of the '314 patent under 35 U.S.C. § 271(a).

(Complaint Pars. 27-29, D.I. 1.) However, any past, present, and future activity performed by Defendants in connection with the development and submission of information to the FDA, including the preparation and filing of the ANDA application, is protected from patent infringement liability under 35 U.S.C. § 271(e)(1) which provides in pertinent part, "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1). Absent any allegations that Defendants have performed activities that are not otherwise protected by § 271(e)(1), Plaintiffs cannot establish an actual controversy to vest this Court with subject matter jurisdiction under the DJA.

In *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938 (N.D. Ill. 1995), the Plaintiff sought a declaratory judgment under 28 U.S.C. § 2201 based on a claim that Defendants were

seeking FDA approval for its generic drug and were taking action directed toward the making, selling or using of its generic drug. 934 F. Supp. at 927, 937-8. The court found the allegations insufficient to state a controversy under Section 2201 because the FDA had not yet even approved the generic form of the drug. *Id.* at 938. The court also refused to exercise jurisdiction over the declaratory judgment claim on policy grounds:

> In sum, this Court refuses to exercise jurisdiction over Plaintiff's declaratory judgment claim because it would undermine Congress' policy in enacting the 1984 Act and because a controversy will only materialize if the FDA approves the accused drug and if the Defendant decides to market the drug. Furthermore . . . Plaintiff does have a cause of action against Defendant pursuant to § 271(a) if Defendant proceeds to manufacture and sell a product that infringes on its '615 patent.

934 F. Supp. at 939. Likewise, a controversy will only "materialize" in this case under Section 271(a) if the FDA approves Apotex Inc.'s ANDA *and* Apotex actually decides to market the drug. However, as explained below, there is a 30-month stay precluding FDA approval of the ANDA, so Plaintiffs' claim that Defendants will start selling infringing drugs once the ANDA is approved lacks the requisite immediacy to give rise to an actual controversy.

By filing Count I in this lawsuit under § 271(e)(2), Plaintiffs have triggered the automatic 30-month stay precluding the FDA from approving Apotex Inc.'s ANDA application until the stay expires. 21 U.S.C. § 355(j)(5)(B)(iii). Courts have held that even shorter periods of time lack sufficient immediacy to give rise to an actual controversy. *See Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938 (N.D. Ill. 1995) (allegation that ANDA applicant could receive approval in three months was insufficient to state a controversy as required by 28 U.S.C. § 2201 because "FDA approval had not been granted at the time that Plaintiff requested declaratory judgment" and there was "no guarantee that the FDA approval will be forthcoming on any particular date in the future."); and *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 05-590-

GMS, 2006 U.S. Dist. LEXIS 57469, at *9 n.3 (D. Del. Aug. 16, 2006) ("the absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate."). Here, Plaintiffs have triggered a statutory stay of FDA approval and have not alleged that the FDA will approve the ANDA application or that the approval is imminent. Therefore, the possibility that the FDA might approve the ANDA application when the 30-month stay expires is insufficient to establish a case or controversy as required by 28 U.S.C. § 2201.

Even if this Court finds that a case or controversy exists, it should exercise its discretion and decline declaratory judgment jurisdiction consistent with the intent of the Hatch-Waxman amendments. "[D]istrict courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995).

The protection from infringement suits until after premarket approval by the FDA is an integral part of Congress' carefully-crafted compromise between brand name companies and generics in the Hatch-Waxman Amendments, the purpose of which is to speed the entry of generic drugs onto the market while protecting the intellectual property rights of brand companies. *See, e.g.*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 n.2 (11th Cir. 2005); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1357-58 (Fed. Cir. 2003). The compromise provided brand companies with, among other things, a patent term extension and data exclusivity. For their part, the generic companies received the aforementioned protection against infringement suits as well as a streamlined application process. Plaintiffs' attempt to circumvent the protection against an infringement suit prior to FDA approval threatens to destroy this compromise.

Exercising declaratory judgment jurisdiction in this circumstance would undermine Congress' policy in enacting the Hatch-Waxman Amendments. As noted by the Court in a comparable case:

> We are concerned that if we exercise jurisdiction over declaratory relief actions in a setting like this, where we have held that defendants are entitled to protection from suit for infringement under § 271(e)(1), we will be undermining one of Congress' purposes in enacting this exemption. . . . [T]he promise by Congress of a safe haven could prove to be completely illusory if the courts permitted competitors to proceed full bore with expensive, resource-draining, and personnel-distracting litigation in the form of actions for declaratory relief. It makes little sense, and thus we assume would be inconsistent with Congress' intent, to protect companies … from suit for actual patent infringement but leave them fully exposed to declaratory relief actions whose gravamen and burdens are much the same.

Intermedics v. Ventritex, Co., 775 F. Supp. 1269, 1290 (N.D. Cal. 1991). In affirming the district court's decision not to exercise its declaratory judgment jurisdiction, the Federal Circuit noted that "exercising jurisdiction over Intermedics' declaratory relief action would undermine the exemption [provided by Section 271(e)(1)] … To permit Ventritex to be protected from direct suit for infringement and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical." *Intermedics v. Ventritex, Inc.*, No. 92-1076, 1993 U.S. App. LEXIS 3620, at *15 (Fed. Cir. Feb. 22, 1993) (unpublished opinion).

Plaintiffs' declaratory judgment claim is nothing more than an attempt to circumvent the protection from infringement suits afforded by the Hatch-Waxman Amendments until after premarket approval by the FDA. Therefore, even if there were sufficient immediacy and reality to establish that Plaintiffs' allegation of future infringement was an actual controversy, the Court should exercise its discretion and decline jurisdiction.

C. THIS CASE SHOULD ALSO BE DISMISSED IF APOTEX INC. PREVAILS ON ITS MOTION TO DISMISS BECAUSE APOTEX INC. IS AN INDISPENSABLE PARTY

In addition to the foregoing, if this Court grants Apotex Inc.'s Motion to Dismiss (filed concurrently herewith), this Case should be dismissed against Apotex Corp. because this case would be lacking an indispensable party—Apotex Inc. Apotex Inc. has filed, concurrently with this Motion, a Rule 12(b)(2) Motion to Dismiss for Lack of Personal Jurisdiction, because Apotex Inc., a Canadian Corporation, has absolutely no contacts with this District or the State of Delaware. Under Fed. R. Civ. P. 19(b), Court may dismiss an action if the Court lacks personal jurisdiction over an indispensable party. In deciding whether to dismiss under this rule, the Court should consider, among other things, the extent to which a judgment rendered in the person's absence might be prejudicial to the person; the extent to which the prejudice can be lessened or avoided by protective measures in the judgment, and whether the plaintiff will have an adequate remedy of the action is dismissed for nonjoinder. Fed.R.Civ.P. 19(b).

In the case at bar, Apotex Inc. is an indispensable party because, as explained above, Apotex Inc. is the ANDA applicant and is the party who must be sued under 35 U.S.C. § 271(e)(2)(A). Assuming Apotex Inc.'s Motion to Dismiss for lack of personal jurisdiction is granted, the case cannot continue against Apotex Corp. alone because as the ANDA filer, Apotex Inc. is in the best position to develop evidence of patent invalidity, and Apotex Inc. would be severely prejudiced if it were unable to participate in this case. Moreover, this prejudice cannot be lessened or avoided because of the absolute nature of the relief sought. In the event that the patent is found valid, Apotex Inc. would likely be bound by any such ruling and the approval of its ANDA would be delayed until the patent expired. Finally, Plaintiffs will have an adequate remedy if the case is dismissed for nonjoinder because Defendants agree that this case can be

transferred to the Middle District of Florida, where a related proceeding involving the same parties in this suit is pending.

A similar result obtained in *Frito-Lay, Inc. v. P&G,* 364 F. Supp. 243, 246-248 (N.D. Tex. 1973). In that case, the plaintiff brought a declaratory judgment suit for non- infringement against the patent owner and the patent owner's subsidiary. The court granted the patent owner's motion to dismiss for lack of personal jurisdiction, and at the same time dismissed the case against the owner's subsidiary even though the subsidiary was subject to personal jurisdiction, because the patent owner was an indispensable party. Thus, in the event Apotex Inc.'s Motion to Dismiss for lack of personal jurisdiction is granted, this case should be dismissed against Apotex Corp. as well, because Apotex Inc. is an indispensable party. *See also Freedom, N.Y., Inc. v. United States,* No. 86 Civ. 1363-CBM, 1986 U.S. Dist. LEXIS 25050 at *13, 5 Fed. R. Serv. 3d (Callaghan) 387 (S.D.N.Y., May. 27, 1986) ("This court having found the absent third party, Cinpac, to be a necessary party within the meaning of Rule 19(a), to be not amenable to the jurisdiction of this court, and to be an indispensable party within the meaning of Rule 10(b), this law suit is dismissed without prejudice pursuant to Fed. R. Civ. P. 12(b)(7) for failure to join an indispensible party.").

V. CONCLUSION

For the reasons stated herein, Defendant Apotex Corp. respectfully requests that the Complaint against it be dismissed for failure to state a claim upon which relief can be granted; for lack of subject matter jurisdiction; and/or for failure to join an indispensable party.

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CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on February 6, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on February 6, 2008, I have Electronically Mailed the document to the following person(s):

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EXHIBIT A

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY